## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

C.R. BARD, INC. and BARD	)
PERIPHERAL VASCULAR, INC.	)
	) C.A. No. 21-349-CFC
Plaintiffs,	)
	)
v.	)
	)
ANGIODYNAMICS, INC.,	)
	)
Defendant.	)

# ANGIODYNAMICS, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS FOR PATENT INELIGIBILITY

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Dated: May 20, 2021 7206763 / 42341-002

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#### **INTRODUCTION**

Asserted U.S. Patent Nos. 9,603,992 and 9,603,993 (Ex. A and Ex. B, respectively)—both titled "Access Port Identification Systems and Methods" claim only the abstract idea of identifying an access port's power-injection capability using a radiopaque message. Bard did not invent power injectable ports or a new type of radiopaque message. Nor did Bard invent radiopaque etching the prior art cited on the face of the patent is filled with examples of etched radiopaque messages. Instead, Bard took preexisting ports, applied longstanding labeling techniques, and changed just one thing—the information conveyed to an observer by the radiopaque message. Patent law does not protect such a trivial modification, which is informational and depends on a mental process. Because Bard claimed nothing new beyond the abstract idea of using conventional radiopaque messages to identify power-injection capability—a preexisting use for ports—the '992 and '993 Patents are ineligible under 35 U.S.C. § 101.<sup>1</sup>

At *Alice* step one, the focal point of the claims is the abstract idea of conveying information using a radiopaque message. The inclusion of conventional port components does not change this conclusion. Nor does the message being

<sup>&</sup>lt;sup>1</sup> The third asserted patent, U.S. Patent No. 8,025,639, is not at issue in this motion. AngioDynamics's motion to dismiss part of the complaint enlarges the time to file an answer or otherwise respond to the remaining allegations in the complaint. *See Cir. City Stores v. Citgo Petroleum Corp.*, No. 92-cv-7394, 1994 WL 483463, at \*4 (E.D. Pa. Sept. 7, 1994).

radiopaque or etched: "radiopaque" simply means "visible on an x-ray," and the patents admit that labeling medical devices with a radiopaque message, including by etching, was well understood at the time of filing. The claims are therefore directed to the abstract idea of conveying information about a port using a radiopaque message—a routine labeling technique. (*See* Part I, *infra*.)

At *Alice* step two, nothing in the claims provides an inventive concept. Indeed, power-injectable ports long predated Bard's patents, accessing veins with ports and catheters was well known, the claimed port structure is generic, and radiopaque messages have long been included on implantable medical devices, including ports. While Bard claims its radiopaque message signifies power-injectability, controlling authority requires Bard to do more than modify the informational content conveyed by a "message" to provide an inventive concept. This is so because the information does not impart any new functionality to the claimed port, which remains power-injectable with or without the radiopaque message. (*See* Part II, *infra*.)

For these reasons, the Court should grant AngioDynamics's motion to dismiss.

#### **LEGAL STANDARD**

#### A. Rule 12(b)(6) Motion to Dismiss Standard

Under Fed. R. Civ. P. 12(b)(6), a complaint must be dismissed when the allegations fail to set forth facts which, if true, would entitle the plaintiff to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While the Court must accept well-pled, non-conclusory factual allegations as true when assessing a motion to dismiss, the Court should not give credence to legal conclusions couched as factual allegations. *Iqbal*, 556 U.S. 678. "Deciding whether a claim is plausible is a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Mgmt. Sci. Assoc., Inc. v. Datavant, Inc.*, C.A. No. 20-502-CFC, 2020 WL 7771156, at \*3 (D. Del. Dec. 30, 2020) (quoting *Iqbal*, 556 U.S. at 679).

Patent eligibility can be determined, in an appropriate case, on a motion to dismiss under Rule 12(b)(6). *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018). This determination need not require a full, formal claim construction. *Id.* Any claim construction disputes need be resolved only "to whatever extent is needed to conduct the § 101 analysis." *Id.* A court need not accept as true allegations that contradict matters properly subject to judicial notice or by exhibit, such as the claims, and patent specification. *Kroy IP Holdings*,

*LLC v. Groupon, Inc.*, C.A. No. 17-1405, 2018 WL 4905595, at \*8 (D. Del. Oct. 9, 2018).

#### B. § 101 Patent Ineligibility Standard

Patent eligibility is a question of law that may depend on underlying facts. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1366-68 (Fed. Cir. 2018). A patent may issue for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. But the Supreme Court has "long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014). Whether a patent claim is ineligible under § 101 is analyzed under the two-step *Alice* test. *See id.* at 217.

### 1. Alice Step One

At *Alice* step one, courts determine whether the patent claims are directed to patent-ineligible subject matter—such as an abstract idea—by "looking at the 'focus' of the claims." *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016). To do so, courts assess the "claims, considered in light of the specification," to determine "whether their character as a whole is directed to excluded subject matter." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016). At step one, courts should "examine the 'focus' of the claim, *i.e.*,

its 'character as a whole," to determine whether a claim is directed to an abstract idea. *Brit. Telecomms. PLC v. IAC/InterActiveCorp*, 381 F. Supp. 3d 293, 304 (D. Del. 2019), *aff'd*, 813 F. App'x 584 (Fed. Cir. 2020). The specification "may help illuminate the true focus of a claim" but "reliance on the specification must always yield to the claim language in identifying the focus." *SynKloud Techs., LLC v. HP Inc.*, 490 F. Supp. 3d 806, 811 (D. Del. 2020).

#### 2. <u>Alice Step Two</u>

Once a claim is held abstract at *Alice* step one, the analysis proceeds to *Alice* step two. At that step, courts consider the claim elements "both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application" that amounts to "significantly more" than a patent on the ineligible concept itself. *Alice*, 573 U.S. at 217-18. If no inventive concept is found, the claim is invalid. In assessing claims, courts are mindful that well-understood, routine, and conventional steps cannot transform an abstract idea into a patentable concept. *Id.* Because the patent-ineligibility inquiry focuses on the language of the claims themselves, features not recited in the claims cannot provide an inventive concept. *See ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 774-75 (Fed. Cir. 2019).

The inventive concept demanded at step two cannot be satisfied by merely implementing an abstract idea using conventional, prior art technology. *Id.* And

"transformation into a patent-eligible application requires more than simply stating the abstract idea while adding the words 'apply it." *Alice*, 573 U.S. at 221; *see Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715 (Fed. Cir. 2014) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 77 (2012)). Nor can printed matter—claimed information that does not transform its claimed substrate into something with new functionality—supply the inventive concept needed at step two. *See In re Marco Guldenaar Holdings B.V.*, 911 F.3d 1157, 1162 (Fed. Cir. 2018).

#### FACTUAL BACKGROUND

#### A. Claim 1 of the '992 Patent Is Representative

Under *Alice*, when multiple claims are substantially similar it is enough to analyze a representative claim. *See*, *e.g.*, *Content Extraction & Transmission LLC v. Wells Fargo Bank*, *N.A.*, 776 F.3d 1343, 1349 (Fed. Cir. 2014); *Two-Way Media Ltd. v. Comcast Cable Commcn's*, *LLC*, 874 F.3d 1329, 1337 (Fed. Cir. 2017). Analyzing a representative claim is particularly appropriate when the claims are directed to the "same concept" and the dependent claims "offer only minor, non-technical variations." *Fast 101 Pty. Ltd. v. Citigroup, Inc.*, 424 F. Supp. 3d 385, 387–88 (D. Del. 2020), *aff'd*, No. 2020-1458, 2020 WL 6947911 (Fed. Cir. 2020).

Claim 1 of the '992 Patent, reproduced below, is representative because it is directed to the overall concept claimed in both patents:

- 1. A venous access port assembly suitable for power injection, comprising:
- a housing having an outlet and a needle-penetrable septum, the housing and septum together defining a reservoir, the housing defining a bottom wall of the reservoir and an outwardly facing bottom surface, the bottom wall comprising a metal;
- a catheter configured for accessing a vein of a patient, the catheter having a lumen in communication with the outlet; and
- a radiopaque alphanumeric message observable via imaging technology subsequent to subcutaneous implantation of the venous access port assembly, the radiopaque alphanumeric message indicating that the venous access port assembly is suitable for power injection, the radiopaque alphanumeric message positioned on the outwardly facing bottom surface etched into the metal.

Claim 2 of the '992 Patent specifies the "imaging technology" as "x-ray technology." And claims 3 through 6 describe the content of the "alphanumeric message," for example, by limiting it to the letters "C" and "T." Claim 7, another independent claim, incorporates these concepts from the dependent claims, as it is substantially similar to claim 1 but recites "x-ray imaging technology" and specifies that the "radiopaque identifier includes letters CT." (*See* Ex. A.)

Claim 1 of the '993 Patent incorporates the same essential concepts as claim 1 of the '992 Patent. As for the other claims, dependent claim 3 identifies the "imaging technology" as "x-ray imaging technology," claim 6 recites that the "housing" comprises a "cap" and "base," and claims 2, 4, 5, and 7-9 specify the appearance of the "radiopaque identification feature." For example, the "feature" may be the letters "CT" or a "symbol," "pattern," or "design." Like claim 7 of the

'992 Patent, independent claim 10 is substantially similar to claim 1 but is limited to "x-ray imaging technology" and a "radiopaque identifier includes letters CT." (See Ex. B.)

Thus, claim 1 of the '992 Patent is directed to the same concept recited in all the claims, and any variations between the claims are minor and non-technical.

#### **B.** Technical Description

#### 1. Bard's Supposed Solution

Rather than claim a new type of port or a new type of radiopaque message, the claims are directed to identification of known capabilities of generic ports using conventional radiopaque messages. That identification is the focus of the claims is underscored by the title of the patents: "Access Port Identification Systems and Methods." On top of that, after describing the state of the art, the background section concludes with the idea that "it would be advantageous to provide an access port which provides at least *one identifiable characteristic* that may be sensed or otherwise determined" following implantation.<sup>2</sup> ('992 Patent, 1:66-2:2.)

To accomplish this supposed solution, the claims rely on age-old labeling techniques. The summary of the invention asserts that an "identifiable feature" may be "perceivable after the access port is implanted within a patient," including

<sup>&</sup>lt;sup>2</sup> All emphasis added unless otherwise noted.

via x-ray. ('992 Patent, 4:5-9, 4:33-34; '993 Patent, 3:32-36, 3:60-61.) And while the specification states that such features "may be correlative to information (e.g., a manufacturer's model or design) pertaining to the access port," such correlation is a fundamental human activity and mental process. ('992 Patent, 4:9-13; '993 Patent, 3:36-40.) Humans have long been able to correlate learned information with information they perceive, and medical professionals have long used radiopaque messages to identify information about implanted medical devices.

#### 2. The State of the Art

Bard did not invent power injectable ports, power injectors, radiopaque messages or even the idea of power injecting implanted ports with contrast medium to improve CT imaging.

Access ports have existed for decades. As the background of the invention explains, they are implanted under a patient's skin and allow clinicians to easily access the patient's bloodstream. ('992 Patent, 1:23-29.) Clinicians access an implanted access port by advancing a needle through the septum into the reservoir, which is also known as the cavity. (*Id.*, 1:40-44.) The outlet of the port connects to a catheter, which extends into the vasculature of the patient, typically terminating in the patient's vena cava. (*Id.*, 1:33-36.)

Power injection refers to the injection of fluids into a patient's bloodstream using a machine called a power injector. ('992 Patent, 3:60-64; '993 Patent, 3:20-

24.) Power injectors allow clinicians to select a flow rate at which to inject fluid—e.g., one milliliter per second. ('992 Patent, 4:1-4; '993 Patent, 3:28-31.) The ability to set a desired flow rate—and to inject fluid at rates that may be difficult to achieve by hand—aids in computed tomography ("CT") scans, as greater imaging clarity can be achieved through the rapid injection of contrast medium. (See '992 Patent, 3:60-4:4; '993 Patent, 3:20-31.)

While the claims include terms like "power-injectable access port," they recite no new or improved structure that supposedly makes a port power injectable. Instead, they claim the same generic port structure that the patents admit long-existed in the prior art: a housing, reservoir/cavity, septum, and outlet stem attached to a catheter. The specification likewise identifies no new structure that would make a port power injectable. For good reason: prior-art access ports having the claimed generic structure were power-injectable and were, in fact, used for power injection before Bard filed its patents.

The same is true for the claimed radiopaque message. The specification describes the routine practice of applying radiopaque messages to a device long understood by those of ordinary skill in the art. (*See* '992 Patent, 11:44-12:10.) Indeed, the face of the patents cite multiple examples of prior art radiopaque messages, including:

• **IsoMed**, which is cited on page 15 of the '992 and page 13 of the '993 Patent. IsoMed is an implantable port that includes an "X-ray

identification tag" showing, among other information, the port's manufacturer, model, and fluid flow rate.

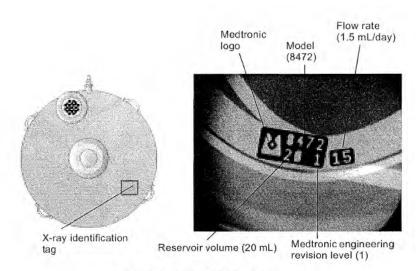
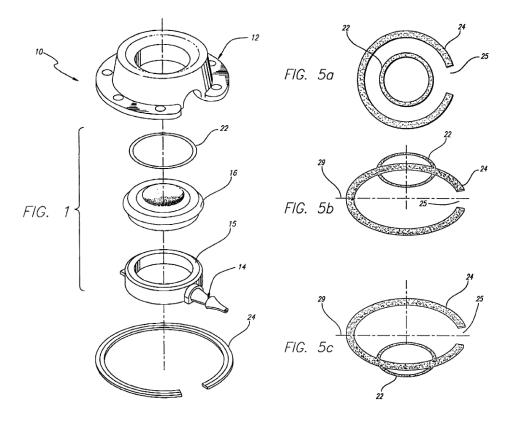
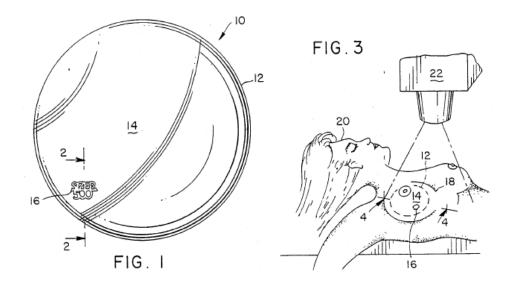


Figure 5. X-ray identification tag.

• **Jones** (US 6,287,293), which is cited on page 4 of both patents. Jones is a Bard patent and describes an implantable access port with "radiopaque rings" applied to the bottom of the port. Jones's radiopaque message shows the port's orientation inside the body.



• Carter (US 4,863,470), which is cited on page 2 of both patents. Carter describes a breast implant that includes a "radiolucent marker" describing the breast implant's cubic volume.



The creation of radiopaque messages by etching was also well understood.

The patents are filled with references that detail how to etch radiopaque messages,

phrases, or other indicators for identification purposes, including:

- **Alberhasky** (US 5,002,735), which is cited on page 3 of the '992 Patent and page 2 of the '993 Patent. Alberhasky describes using engraving to reduce the density of markings so that they "can be seen radiographically, such as on [an] x-ray."
- **Sayre** (US 6,826,257), which is cited on page 5 of the '992 Patent and page 4 of the '993 Patent. Sayre describes photoetching, stamping, or laser cutting a radiopaque material to create "radiopaque marking indicia" including letters and words, which are used, as one example, to "indicate the orientations of specimens" under x-ray.
- **Sheldon** (US 4,529,635), which is cited on page 2 of both patents. Sheldon describes indenting a lead-backed tape to create "individual characters [that] will stand out on the radiograph."
- **Samis** (US 4,406,567), which is cited on page 2 of both patents. Samis describes an engraving tool used to engrave letters into identification chips "fabricated of radiographically opaque material[.]"
- **Wiedenhoefer** (US 6,459,772), which is cited on page 4 of both patents. Wiedenhoefer describes a "radiographic reference marker" that includes an attenuation plate that can be etched with designs or alphanumeric characters that will appear as images on an "irradiated radiographic film."

It was also routine to apply a radiopaque message to the bottom of a port. During the prosecution of the '992 and '993 Patents' parent, U.S. Patent No. 7,785,302 (the "'302 Patent"), Bard sought to provoke an interference between the

'302 Patent<sup>3</sup> and the patent application of a competitor by submitting a sworn declaration stating the following:<sup>4</sup>

- "There are only a limited number of locations where radiopaque markings can be placed on the venous access port." (Ex. C, Eliasen Declaration ¶27.)
- "The outside surface of the housing base location would have been obvious to try, as evidenced by the fact that nearly every port has a lot number and/or company logo printed, embossed, engraved, etc. on the bottom of the housing base." (*Id.* ¶38.) As a result, "one of ordinary skill in the art...would have immediately thought to put the radiopaque markings on the housing base." (*Id.*)

#### C. Relevant Litigation History

The litigation history between the parties helps clarify why the claims are ineligible under *Alice* and its progeny. Bard has been suing AngioDynamics for nearly ten years on patents covering the same subject matter. On top of this case and C.A. No. 20-1544, which was recently transferred from the District of Utah and assigned to Your Honor, Bard also sued AngioDynamics in Delaware in 2015. That case, C.A. No. 15-218, concerns patents covering similar subject matter—so-called power-injectable ports and certain "features" for identifying the port's

<sup>&</sup>lt;sup>3</sup> The '302 Patent is one of the patents asserted by Bard against AngioDynamics in C.A. No. 20-1544 assigned to Your Honor.

<sup>&</sup>lt;sup>4</sup> Bard provoked the interference it wanted using this declaration and ultimately prevailed on the merits. Bard is therefore estopped from taking a contrary position here. *See Trs. of Columbia Univ. v. NortonLifeLock, Inc.*, No. 3:13-cv-808, 2019 WL 7040931, at \* 5 (E.D. Va. Dec. 20, 2019) (estopping a party from applying a narrow claim interpretation after advancing a broader interpretation during a successful *inter partes* review).

power-injection capability. The patents asserted there likewise claim an identification system for identifying power injectable ports but are not genealogically related to the '992 and '993 Patents, as they claim priority to different provisional and non-provisional applications.

The patents in the 2015 case have been extensively litigated, including at the Federal Circuit. Throughout the 2015 case, Bard maintained that it invented power injectable ports and that the information conveyed by its claimed "radiographic markers"—*i.e.*, that its claimed ports were power injectable—was entitled to patentable weight under the printed matter doctrine. But the Federal Circuit foreclosed both arguments in its 2020 decision:

#### **Power-Injectable Ports**

- "At the time [of the invention,] Bard's commercially marketed vascular port product was already structurally suitable for power injection[.]" *C. R. Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1375 (Fed. Cir. 2020) (Ex. D).
- "As of 2005 . . . medical providers were using existing ports for power injection." *Id*.
- "[P]rior art ports, and the use of those ports, satisfied most of the remaining elements of the asserted claims, including power injectability[.]" *Id.* at 1384.

#### **Printed Matter**

• The claim limitations directed to the use of identifiable features to identify power-injection capability violate the printed matter doctrine. *Id.* at 1382.

In upholding this Court's printed matter ruling, the Federal Circuit wrote: "the asserted claims [in the 2015 case] contain printed matter that is not functionally related to the remaining elements of the claims[.]" *Id.* at 1381. It explained that "the content of the information conveyed by the claimed markers— *i.e.* that the claimed access ports are suitable for injection at the claimed pressure and flow rate—is printed matter not entitled to patentable weight." *Id.* at 1382. Thus, the information conveyed by the identification limitations—*i.e.*, that the port is power injectable—cannot provide an inventive concept under *Alice* step two.

Because the claims of the '992 and '993 Patents also include limitations directed to the identification of power-injectability, this conclusion of law should apply with equal force here. In fact, another court did just that when analyzing patents in the same family as those asserted here. *See C.R. Bard, Inc. v. Medical Components, Inc.*, No. 2:17-cv-00754, 2020 WL 6902367, at \*10 (D. Utah. Nov. 24, 2020) (Ex. E). Like the Federal Circuit, that court held that "regardless of the specific wording or symbols used, the 'identifier' or 'message' must indicate that a port is power injectable. It follows that the 'identifier' and 'message' limitations are directed to the content of information." 2020 WL 6902367, at \*23. The court further held that these limitations "do not have a functional relation to the substrate," meaning they were not entitled to patentable weight. *Id*.

While the Federal Circuit reversed this Court's patent ineligibility holding in the 2015 case, it did so because the claims were not "solely" directed to printed matter. *Id.* at 1384. But the Court did not decide whether the claims were directed to an abstract idea at step one, as the District Court analyzed the claims under the printed matter doctrine and not under the two-step *Alice* framework. (*See* C.A. No. 15-218, D.I. 416 at 5.)

At step two, the Federal Circuit determined that on the record before it, there was insufficient evidence for it to conclude that the use of radiographic markers on ports was routine and conventional. But the Federal Circuit held that:

- The "use of radiographically identifiable markings on implantable medical devices was known in the prior art." *Id.*
- The prior art included a "vascular port with an x-ray tag that identified the port's flow rate." *Id*.
- Prior art ports included "external identifiers" that identified the port to practitioners. *Id*.

Here, the '992 and '993 Patents do not recite a "radiographic marker" like the claims in the 2015 case. Instead, they claim an etched radiopaque message/identifier which was not only long-known and well-understood, but could also be created through routine and conventional practices. (*See* '992 Patent, 11:41-12:10; '993 Patent, 12:47-51.) At any rate, "[b]y its own admission, Bard did not invent radiopaque markings on subcutaneous medical devices for identification by x-ray or other imaging (*see* D.I. 515 at 4), and it does not claim

any imaging technology or the generic use of radiopaque markings for conveying any and all types of messages." (*Id.*)

#### **ARGUMENT**

## I. Alice Step One: The Claims Are Directed to the Abstract Idea of Identifying Information About a Port

The claims are directed to identifying information relating to power-injection capability using a "radiopaque" message. Little detail is given about this message, how it is understood as signifying power-injectability, or what messages *would not* fall within the claims. The centerpiece of the claims is therefore a black box, underscoring their preemptive nature. *See Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1302 (Fed. Cir. 2020) ("[A claim] must go beyond stating a functional result; it must identify 'how' that functional result is achieved by limiting the claim scope to structures specified at some level of concreteness.").

The claimed "message" is much like the abstract "unique identifier" in Secured Mail Sols. LLC v. Universal Wilde, Inc., 873 F.3d 905, 907 (Fed. Cir. 2017). In Secured Mail, the "unique identifier" was a "barcode," "QR code," or "URL" affixed to a "mail object (e.g., an envelope or package)" that conveyed mail-related information when scanned, such as "the sender, recipient, and contents." Id. at 910-11. The patentee alleged that its claims were not abstract because they "improved on" the prior art by facilitating the mail process. Id. at 910. But the claims were not "directed to" any concrete advancement, such as "a

new barcode format" or "an improved method of generating or scanning barcodes." *Id.* Instead, they "embrace[d] the abstract idea of using a marking affixed to the outside of a mail object to communicate information about the mail object" using non-specific, results-oriented language. *Id.* at 911.

So too here: just as the *Secured Mail* claims embraced the abstract idea of using associated markings to convey information about a mail object, Bard's claims embrace the abstract idea of using conventional radiopaque messages to convey information about a port. Just as in *Secured Mail*, Bard's claims do not recite an advancement over the prior art, such as a new or improved radiopaque message or identifier, that might save them from abstractness. Instead, they use non-specific, results-oriented language—that a vague radiopaque "message" identifies the port as power-injectable—without "any limitation on how to produce that result." *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1345 (Fed. Cir. 2018) ("Instead of claiming a solution for producing that result, the claim in effect encompasses all solutions.").

Secured Mail is no outlier. In *In re Rudy*, 956 F.3d 1379, 1384 (Fed. Cir. 2020), the Federal Circuit invalidated claims directed to the "abstract idea of selecting a fishing hook based on observed water conditions." Rather than claim some concrete advancement over the prior art, the claims required "nothing more than collecting information . . . and analyzing that information"—which represent

"mental processes akin to data collection or analysis." *Id.* Bard's claims similarly depend on a mental step: stripped of Bard's attempts to cloak them in the language of power injection, they are directed to reading a message to identify information about a use for ports that already existed in the art.

The claims cannot be saved from abstractness simply because they recite a generic port and claim a conventional radiopaque message created using conventional etching. In *ChargePoint*, 920 F.3d at 774-75, apparatus claims were invalidated as abstract even though they recited specific limitations directed to electric vehicle charging stations. Despite these generic recitations of electric vehicle charging structure, the "broad claim language would cover any mechanism for implementing network communication on a charging station" (id. at 770), much like the black box "message" limitation here. "Etching" the radiopaque message on the bottom of the port does not remedy this infirmity, as it merely references a well-known technique for creating x-ray visible characters. (See State of the Art, supra.) Similarly here, Bard has already admitted that a skilled artisan would immediately think to locate the message on the bottom of the port. (See Ex. C. (Eliasen Declaration).) Thus, like the patentee in *ChargePoint*, Bard "stopped short" of providing the level of specificity needed to survive *Alice*. *Id*. at 770.

#### II. Alice Step Two: The Claims Contain No Inventive Concept

The claimed port structure is generic, power-injecting ports was wellunderstood at the time of the invention, and labeling medical devices with radiopaque messages is conventional. All that Bard could point to as "inventive" at step two is the identification of power-injection capability—the informational content of the claimed message. But identifying information about a port is the "abstract idea itself," which "cannot supply the inventive concept." ChargePoint, 920 F.3d at 774. Moreover, just as the "generic networking capabilities" in ChargePoint did "nothing to improve how charging stations function" (920 F.3d at 774-75), the claimed message does not improve how the port functions. Instead, the "claims here simply recite that the abstract idea will be implemented using conventional components and functions generic to the technology." Free Stream Media Corp. v. Alphonso, Inc., No. 2019-1506, 2021 WL 1880931, at \*8 (Fed. Cir. May 11, 2021). That approach cannot provide an inventive concept at step two.

The claims lack an inventive concept for an additional reason: the message's informational content is also unpatentable printed matter, as another court in this District, the Federal Circuit, and the District of Utah have already held. For example, in *Guldenaar*, 911 F.3d at 1162, the Federal Circuit concluded "the only arguably unconventional aspect" of an abstract claim was its "printed matter," which could not provide an inventive concept. The *Guldenaar* claims recited the

use of three specialized dice, where the first die had a "marking" on only a single face, the second die had identical "markings" on two faces, and the third die had identical "markings" on three faces. *Id.* at 1159. After determining that the claims were directed to the abstract idea of playing a wagering game, the Federal Circuit rejected the argument that the specialized die markings were unconventional. *Id.* at 1161. Instead, the die markings "constitute[d] printed matter, which "falls outside the scope of § 101." *Id.* They "communicate[d] information to participants indicating whether the player has won or lost a wager, similar to the markings on a typical die or a deck of cards." *Id.* And this new information "d[id] not cause the die itself to become a manufacture with new functionality." *Id.* 

Just as the die markings in *Guldenaar* communicated information about winning or losing a game, the claimed message here merely communicates a port's power injection capability. But just as *Guldenaar*'s markings did not transform the die itself, Bard's message does not change how the port functions. Indeed, a port is power-injectable whether or not it includes a label or message identifying this intrinsic capability. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1065 (Fed. Cir. 2010) (holding that FDA-required instructions did not create functional relationship to drug); *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010) (same for step of "informing" patient about properties of drug). And according to the specification, the radiopaque message would be placed on

ports that are known to be power-injectable, obviating any argument that the message confers power-injectability. ('992 Patent, 4:16-23; '993 Patent, 3:43-50.) For these reasons, the radiopaque message is printed matter that does not transform the claimed port. That it communicates different information than before therefore cannot provide the inventive concept *Alice* demands.

Moreover, like the *Guldenaar* die markings, the prior art is replete with examples of radiopaque messaging on medical devices, including messages created with etching. (*See* State of the Art, *supra*.) In fact, the specification of the '992 Patent contains no meaningful disclosure about etching, and the specification of the '993 Patent makes clear that etching is routine and conventional. ('993 Patent, 12:47-51 (explaining that multiple known methods can be used to create the etched radiopaque marker); *id.*, 12:67-13:4 (explaining that one skilled in the art would understand how to vary engraving depth). Notably, Bard itself has already admitted that a skilled artisan would have immediately thought to locate the message on the bottom of the port. (*See* Ex. C.)

Thus, the claims fail both steps of the *Alice* test.

#### **CONCLUSION**

For these reasons, the Court should grant AngioDynamics's motion to dismiss.

## Respectfully submitted,

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Dated: May 20, 2021 7206763 / 42341-002

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